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Gregory Durand

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EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

05/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/533,982

Applicant(s)

DURAND ET AL.

Examiner

Elli Peseelev

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 5-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

The disclosure is objected to because of the following informalities: the specification on page 1 fails to state that this case is a 371 of PCT/FR03/0335.

Appropriate correction is required.

Claims 3 and 4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 1, 2008.

Claims 1 and 5-14 have been examined only insofar as the elected species is concerned.

Claims 6-7 are objected to because of the following informalities: a period is missing at the end of claims 6-7. Appropriate correction is required.

Claims 1, 2 and 5-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the variable X representing glucosamine, sucrose and lactobionamide, for variables Y representing spacer groups as set forth on page 11 of the specification and for variable Y' representing variables as set forth on page 6 of the specification and does not reasonably provide enablement for polysaccharides and amino derivatives of monosaccharides and polysaccharides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would

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not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

The claims encompass an enormous number of compounds.

For example, the term "polysaccharide" encompasses long chain carbohydrates such as starch, cellulose, chitin, hyaluronic acid, etc. The disclosure of two disaccharides i.e. sucrose and lactobionamide does not provide an adequate support for the term "polysaccharides". Further, note that the variables Y and Y' are not limited to any number of carbon atoms and therefore encompass long chain molecules while the specification provides support for only short chain molecules.

(B) The amount of direction provided by the inventor.

The specification discloses two specific disaccharides i.e. sucrose and lactobionamide. However, this guidance is not commensurate with the full scope of the term "polysaccharides". Also the disclosure of short chain spacer groups "Y" and "Y'" is not commensurate in scope with the claimed compounds of unlimited chain length.

(C) The existence of working examples.

The specification on page 20 provides four specific compounds which have the desired biological activity.

(D) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori which compounds will be active from the specification or chemical structures alone, an extraordinary amount of trial and error experimentation is required to identify the active compounds.

Claims 9-11 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

Claim 9 reads on preventing and/or treating the effects of free radicals.

Claim 10 reads on preventing or treating the pathological conditions linked to oxidative stress and the formation of oxygen-containing free species.

Claim 11 reads on preventing immune and inflammatory diseases, the ischemia-reperfusion syndrome, atherosclerosis, Alzheimer's disease, Parkinson's disease, lesions due to UV and ionizing radiations, Huntington's disease, cancers and cellular aging.

Claim 13 reads on preventing and/or treating the effects of aging.

(B) The existence of working examples.

The disclosure on page 16 of the specification is directed to measuring the ability of a single compound Nitrone A1 to trap free radical species.

The disclosure on page 17 of the specification is directed measuring the biological antioxidant and anti-free radical if a single compound Nitrone A2 in vitro.

The disclosure on page 20 of the specification is directed to contractile activity of the muscle fibers of four specific compounds (Nitrones A1, A2, A3 and A4). Said disclosure is not commensurate in scope with preventing and treating conditions and diseases encompassed by the present claims.

(C) The level of predictability in the art.

There is no known correlation between the data set forth in the specification and the prevention and treatment of any specific disease or condition.

(D) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori which specific compounds will be active in preventing and/or treating which specific disease from the specification or chemical structures alone, an extraordinary amount of trial and error experimentation is required to identify the specific activity having the specific biological activity.

Claims 9-11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-11 and 14 provide for the use of a compound according to the formula (I) of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9-11 and 14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623